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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,866	MOREIN ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2008 has been entered.

Oath and Declaration

2. In view of the papers filed 9-9-2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Kefef Hu.

Amendment Entry

3. The amendment filed October 27, 2008 is acknowledged. Claim 1 has been amended. Claims 1-14 are pending and are currently under examination.

Rejections Withdrawn

4. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Objection to claim 3 under 37 CFR 1.75 (c), as being improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of applicant's argument.

Claim Rejections Maintained- 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 1-2, 4-9, and 14 under 35 U.S.C. 102(b) as being anticipated by Friede et al ((US Patent No. 6,558,670 Publication Date May 6, 2003) is maintained for the reasons set forth in the previous office action.

Applicant arguments:

A) Applicant notes that claim 1 has been amended to recite, inter alia, "intraperitoneally or subcutaneously administering". First, the adjuvants, when integrated into ISCOM or ISCOM matrix are in separate particles.

B) Applicant submits that Fraction A of Quil A is non-haemolytic and activates dendritic cells. This activation helps both the antigen and other immune stimulating adjuvants to further activate the immune response. To the contrary, Friede et al results who clearly the potential of intranasal formulations combining a lytic saponin and an immunostimulant. The administration route has been limited so that an intranasal route, which is less effective for fraction A of Quil A, is no longer within the scope of the claims.

C) Attachment 1: Applicant has tested fraction A and C from Quil A. It is evident that Fraction A of Quil A does not improve the IgA titre in intranasal administration contrary to Friede et al.

Attachment: Applicant demonstrates the IgG titre after intranasal administration of OVA and different ISCOM matrixes. It is evident that Fraction A and C in different particles give a lower IgG titre than ISCOM matrix made of mixture of Quil A saponins and fraction A and C in the same ISCOM matrix after intranasal administration.

Examiner's Response to Applicant's Arguments:

A) Applicant's arguments have been considered but have not been found persuasive. The claims are drawn to a method of enhancement of an immune response and immunomodulating activity comprising intraperitoneally or subcutaneously

administering to a subject effective of an adjuvant composition synergistic effect comprising an ISCOM particle comprising fraction A of Quil A together with at least one other adjuvant is in free form or integrated into another separate ISCOM particle other than the one in which the fraction A of Quil A was integrated. Friede et al does not differ in any way. Examiner interprets the claim to comprise fraction A Quil A with at least one other adjuvant in free form or to comprise fraction A Quil A with at least one other adjuvant integrated in an ISCOM particle. However it is unclear what constitutes a single ISCOM particle as stated from the preamble. Furthermore it is unclear if fraction A Quil A is always contained in an ISCOM particle or not.

Friede et al teach that their composition can be administered subcutaneously (see column 8 lines 46-54). Consequently, there is no discernable difference between the composition of disclosed in the art and the claimed composition.

B) As to Applicant's Assertion, administration route has been limited so that an intranasal route, which is less effective for fraction A of Quil A, is no longer within the scope of the claims. Fraction A is defined in the specification by disclosing the preparation of Fraction A (see pg. 8 lines 1-20) but is silent with regard to its constituent components. Moreover, "Fraction A" is a laboratory designation and conveys no structure. Thus Fraction A is not defined in the specification with any structural limitations. Therefore fraction A of Quil A as taught by Friede et al meets the limitations of the claims.

C) As to Attachments 1 and 2, the data in Attachment 1 and 2 are not considered as it was not presented in a properly executed declaration. As such it constitutes an attorney's statement which does not constitute evidence (see MPEP § 409.03(b)).

As outlined previously, the instant claims a method of enhancement of an immune response and immunomodulating activity comprising intraperitoneally or subcutaneously administering to a subject effective of an adjuvant composition synergistic effect comprising an ISCOM particle comprising fraction A of Quil A together with at least one other adjuvant is in free form or integrated into another separate ISCOM particle other than the one in which the fraction A of Quil A was integrated.

Friede et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect (see column 3 lines 1-5, see column 10 lines 30-60), comprising: an ISCOM particle comprising a fraction A of Quil A; and together with at least one other adjuvant (CpG) (see example 1). Fried et al teach that the CpG used in the adjuvant combinations (see column 3 lines 25-65) of the present invention may be in free solution or may be complexed to ISCOMs (see column 9 lines 30-67). Friede et al teach that the CpG and saponin in the adjuvants or vaccines of the present invention may be separate or associated (see column 9 lines 30-67).

Friede et al teach that the haemolytic saponin preparations will further be combined with other adjuvants including Monophosphoryl Lipid A (see columns 9 lines 50-56) therefore the method of Fried et al teach the method according to claim 1 wherein said one other adjuvant is monophosphoryl lipid A and the method according to claim 7 wherein said at least one other adjuvant is at least one of Monophosphoryl Lipid A. Friede et al teach the method wherein said ISCOM particle is an ISCOM complex (Quil A, cholesterol, adjuvant), (see column 8 lines 60-65, column 4 lines 9-15) wherein in the composition further comprises a pharmaceutically acceptable carrier (see abstract, see column 10 lines 65-67). Friede et al teach the newly added limitations "intraperitoneally or subcutaneously administering" (see column 8 lines 46-54).

Therefore, Friede et al anticipates all the claim limitations of the rejected claims.

Claim Rejections Maintained- 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Friede et al (U.S. Patent No. 6,558,670) in view of Cox et al (WO 96/11711) for the reasons set forth in the previous Office action in the rejection of claims 1, 3 and 10-13.

Applicant arguments:

A) Cox does not disclose separation of the Quil A fractions into separate particles. Even though the document appears to mention an ISCOM matrix, it does not disclose that different types of saponin fractions may be integrated into different ISCOM matrix particles or that this should bring about any advantages. In view of the fact that fraction A is the major part of the 703 preparations such mixtures should be considerably less haemolytic than Quil A and fraction C in ISCOM s or ISCOM - matrix preparations. Thus, Applicant respectfully submits that the instant claims are not rendered obvious by the cited documents.

Examiner's Response to Applicant's Arguments:

A) Applicant's arguments have been considered but have not been found persuasive.

As Applicant's assertion that the reference fails to state that different types of saponin fractions may be integrated into different ISCOM matrix particles. As to

Applicant's assertion that, one would expect a combination of 70% A and 30 % C in the same ISCOM complex to give:

$$\frac{70*800+30*20}{100} = 566\text{ug/ml}$$

Cox et al. teaches saponin preparation of saponins of Quillaja saponaria from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C (claims 1-3), fractions A, B, and C (page 7, line 24). A method of preparing an immunostimulatory complex (ISCOM), which comprises admixing a saponin preparation according to saponins Quillaia saponaria comprising from 50-70% by weight of Fraction A of Quil A and from S0-30% by weight of Fraction C of Quil A (Claims 10, 1). Cox et al. teaches ISCOMs are Immuno Stimulating Complexes, where the typical ISCOM is estimated to contain 5 to 10% by weight Quil A, 1 to 5% cholesterol and phospholipids, and the remainder proteins. Peptides can be
incorporated into ISCOMs either directly or by chemical coupling to a carrier protein after incorporation of the carrier protein into ISCOMs (column1, lines 40-56). This whole complex confers the immunostimulatory effects. Table 1 shows fractions A, B, and C of Quil A displaying different ISCOM forming ability and adjuvant activity. Cox et al. show that particular combinations of fraction A and C result in a saponin preparation which has the desirable properties of A and the benefits of C (column 5, lines 25-31). Thus this shows that different types of saponin fractions are used to form different ISCOMs. Table 5 shows virus and ISCOMs, virus and ISCOM-matrix, and virus alone as adjuvants to confer immunogenicity. Thus the reference teaches that there are different types of ISCOMs with different types of formulations and different proteins to form the desired ISCOM matrices.

KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding a obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82

USPQ2d at 1396) available at
(http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

The instant claims a method of enhancement of an immune response and immunomodulating activity comprising intraperitoneally or subcutaneously administering to a subject effective of an adjuvant composition synergistic effect comprising an ISCOM particle comprising fraction A of Quil A together with at least one other adjuvant is in free form or integrated into another separate ISCOM particle other than the one in which the fraction A of Quil A was integrated.

Friede et al is relied upon as set forth supra

Friede et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect (see column 3 lines 1-5, see column 10 lines 30-60), comprising: an ISCOM particle comprising fraction A of Quil A; and together with at least one other adjuvant (CpG) (see example 1). Fried et al teach that the CpG used in the adjuvant combinations (see column 3 lines 25-65) of the present invention may be in free solution or may be complexed to ISCOMs (see column 9 lines 30-67). Friede et al teach that the CpG and saponin in the adjuvants or vaccines of the present invention may be separate or associated (see column 9 lines 30-67).

Friede et al teach that the haemolytic saponin preparations will further be combined with other adjuvants including Monophosphoryl Lipid A (see columns 9 lines 50-56) therefore the method of Fried et al teach the method according to claim 1 wherein said one other adjuvant is monophosphoryl lipid A and the method according to claim 7 wherein said at least one other adjuvant is at least one of Monophosphoryl Lipid A. Friede et al teach the method wherein said ISCOM particle is an ISCOM complex (Quil A, cholesterol, adjuvant), (see column 8 lines 60-65, column 4 lines 9-15) wherein in the composition further comprises a pharmaceutically acceptable carrier (see abstract, see column 10 lines 65-67). Friede et al teach the newly added limitations "intraperitoneally or subcutaneously administering" (see column 8 lines 46-54).

However Friede et al does not teach a method, wherein the saponin fraction from Quil A is fraction C of Quil A or fraction B of Quil A, wherein ISCOM particle is ISCOM matrix complex, wherein the composition comprises 50-99.9% of fragment A of Quil A; and 0.1-50% of a fraction or derivative of Quil A based on the total weight of the composition, wherein the composition comprises 75-99.9% of fragment A of Quil A; and 0.1-25% of a fraction or derivative of Quil A based on the total weight of the composition, wherein the composition comprises 91-99.1% of fragment A of Quil A; and 0.1-9% of a fraction or derivative of Quil A based on the total weight of the composition.

Cox et al teaches a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect (see pgs. 9-24). The method of Cox et al teaches that an ISCOM matrix can have at least one immunogen (adjuvant), incorporated into or associated with the ISCOM matrix. Therefore the method of Cox et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an ISCOM particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate ISCOM particle, wherein at least one other adjuvant is integrated into one ISCOM particle (see pg. 3 lines 20-30, pgs. 4-5). Cox et al teach the method wherein the saponin fraction from Quil A is fraction B of Quil A, wherein said ISCOM particle is an ISCOM complex, wherein said ISCOM particle is an ISCOM matrix complex (see page 7 line 24).

It would have been obvious to one of skill in the art to use the ISCOM matrix complex (as disclosed by Cox et al) as the ISCOM particle as taught by Friede et a in order to take advantage of the reduced Quil A toxicity associated with the use of said complexes.

One would have had a reasonable expectation of success because the ISCOM matrix (as disclosed by Cox et al) has been shown to have a significant adjuvant effect and reduced toxicity as well as (see page 1).

As to the limitation of 11-13 is drawn to a method according to claim 3, wherein the composition comprises 50-99.9% of fragment A of Quil A; and 0.1-50% of a fraction or derivative of Quil A based on the total weight of the composition (claim 11), wherein the composition comprises 75-99.9% of fragment A of Quil A; and 0.1-25% of a fraction or derivative of Quil A based on the total weight of the composition(claim 12), wherein the composition comprises 91-99.1% of fragment A of Quil A; and 0.1-9% of a fraction or derivative of Quil A based on the total weight of the composition (claim 13). Cox et al. teaches saponin preparation of saponins of Quillaja saponaria from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C, fractions A, B, and C (page 7, line 24). However, it does not teach the specific percentage weight claimed.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

New Grounds of Objections/Rejections

Objections

7. Claims 1-7 and 9-10 is objected to because of the following informalities: As to claim 1-7 and 9-10, the claim contains the acronym “iscom”. While acronyms are

permissible shorthand in the claims, the acronym should be capitalized and the first recitation should include the full recitation followed by the acronym in parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claim is drawn to a vast genus of fractions or derivatives of Quil A and is silent with regard to what "fraction derivative of Quil A" will act synergistically with "fragment A of Quil A". To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so

as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of fractions or derivatives of Quil A with regard to what "fraction or derivative of Quil A" will act synergistically with "fragment A of Quil A". Applicant must also give a structural and functional limitation.

The specification, however, does not disclose distinguishing and identifying features of a representative member of the genus of fractions or derivatives of Quil A with regard to what "fraction or derivative of Quil A" will act synergistically with "fragment A of Quil A" which the claims are drawn, such as a correlation between structure of the peptide and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus.

MPEP § 2163.02 states, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc.'v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "'Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104).

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of genus of fractions or derivatives of Quil A with regard to what "fraction or derivative of Quil A" will act synergistically with "fragment A of Quil A", the skilled artisan could not immediately recognize or distinguish members of the claimed genus. Therefore, in accordance with the Guidelines, the description of genus of fractions or derivatives of Quil A with regard to what "fraction or derivative of Quil A" will act synergistically with "fragment A of Quil A" is not deemed representative, thus the claims does not meet the written description requirement. ,

Deleted: ¶

Claims 1, 4-7, and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. As to claims 1 and 4-6, recites the phrase "particles". Applicant has attempted to claim the number of particles that the composition contains. It is unclear how to interpret if the applicant claiming that the composition contains a single ISCOM particle or a single homogenous population?. For example, the composition can comprise fraction A Quil A with at least one other adjuvant in free form in an ISCOM particle or fraction A Quil A with at least one other adjuvant in free form integrated in separate ISCOM particles. For example , the claim does not distinguish fraction A of Quil A and at least one other adjuvant as being in separate ISCOM particles. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of the claim language regarding the number of particles as set forth supra or how to assess such.

10. As to claims 1, 5, 7, and 11-13 ; the claims recites the phrase "fragment A of Quil A". However, neither the claim nor the specification clearly defines nor sets forth the meaning or means to assess " fragment A of Quil A". Prior art states that "fragment A of Quil A" is defined in the art as selective, specific, or nonspecific with respect to cells.

Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "fragment A of Quil A" nor how to assess such. It is unclear how to interpret what is considered "fragment A of Quil A" and inasmuch as it is not a recognized term and not defined in the specification.

11. Claims 11-13 recites the limitation "fragment A of Quil A". There is insufficient antecedent basis for this limitation in the claim.

Status of the Claims

13. No claims are allowed.
Claims 1-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner

GAU 1645

REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645